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DEPARTMENT OF EDUCATION

Disability and Rehabilitation Research Projects and Centers Program; Traumatic Brain Injury Model Systems Centers

AGENCY: Office of Special Education and Rehabilitative Services, Department of Education.

ACTION: Notice.

Overview Information:

CFDA Number: 84.133A-5.

Final priority; National Institute on Disability and Rehabilitation Research (NIDRR)--Disability and Rehabilitation Research Projects and Centers Program--Disability Rehabilitation Research Project (DRRP)--Traumatic Brain Injury Model Systems Centers.

SUMMARY: The Assistant Secretary for Special Education and Rehabilitative Services announces a priority for the Disability and Rehabilitation Research Projects and Centers Program administered by the National Institute on Disability and Rehabilitation Research (NIDRR).

Specifically, this notice announces a priority for Traumatic Brain Injury Model Systems (TBIMS) Centers. The Assistant Secretary may use this priority for a competition in fiscal year (FY) 2012 and later years. We take this

action to focus research attention on areas of national need.

EFFECTIVE DATE: This priority is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Marlene Spencer, U.S. Department of Education, 400 Maryland Avenue, SW., room 5133, Potomac Center Plaza (PCP), Washington, DC 20202-2700. Telephone: (202) 245-7532 or by e-mail: marlene.spencer@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1-800-877-8339.

SUPPLEMENTARY INFORMATION:

This notice of final priority is in concert with NIDRR's currently approved Long-Range Plan (Plan). The Plan, which was published in the Federal Register on February 15, 2006 (71 FR 8165), can be accessed on the Internet at the following site:

[www.ed.gov/about/offices/list/osers/nidrr/policy.html](http://www.ed.gov/about/offices/list/osers/nidrr/policy.html).

Through the implementation of the Plan, NIDRR seeks to: (1) improve the quality and utility of disability and rehabilitation research; (2) foster an exchange of expertise, information, and training to facilitate the advancement of knowledge and understanding of the unique

needs of traditionally underserved populations; (3) determine best strategies and programs to improve rehabilitation outcomes for underserved populations; (4) identify research gaps; (5) identify mechanisms of integrating research and practice; and (6) disseminate findings.

This notice announces a final priority that NIDRR intends to use for a DRRP competition in FY 2012 and possibly later years. However, nothing precludes NIDRR from publishing additional priorities, if needed. Furthermore, NIDRR is under no obligation to make an award for this priority. The decision to make an award will be based on the quality of applications received and available funding.

Purpose of Program:

The purpose of the Disability and Rehabilitation Research Projects and Centers Program is to plan and conduct research, demonstration projects, training, and related activities, including international activities; to develop methods, procedures, and rehabilitation technologies that maximize the full inclusion and integration of individuals with disabilities into society, employment, independent living, family support, and promote economic and social self-sufficiency of individuals with

disabilities, especially individuals with the most severe disabilities; and to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended (Rehabilitation Act).

#### Disability and Rehabilitation Research Projects (DRRPs)

The purpose of DRRPs, which are funded under NIDRR's Disability and Rehabilitation Research Projects and Centers Program, is to improve the effectiveness of services authorized under the Rehabilitation Act of 1973, as amended, by developing methods, procedures, and rehabilitation technologies that advance a wide range of independent living and employment outcomes for individuals with disabilities, especially individuals with the most severe disabilities. DRRPs carry out one or more of the following types of activities, as specified and defined in 34 CFR 350.13 through 350.19: research, training, demonstration, development, dissemination, utilization, and technical assistance. Additional information on DRRPs can be found at:

<http://www2.ed.gov/rschstat/research/pubs/res-program.html#DRRP>.

Program Authority: 29 U.S.C. 762(g) and 764(a).

Applicable Program Regulations: 34 CFR part 350.

We published a notice of proposed priority for this program in the Federal Register on March 7, 2012 (77 FR 13578). That notice contained background information and our reasons for proposing the particular priority.

Public Comment: In response to our invitation in the notice of proposed priority, four parties submitted comments on the proposed priority.

Generally, we do not address technical and other minor changes. In addition, we do not address general comments that raised concerns not directly related to the proposed priority.

Analysis of Comments and Changes: An analysis of the comments and of any changes in the priority since publication of the notice of proposed priority follows.

Comment: One commenter requested that NIDRR revise paragraph (a) of the priority to identify standards or guidelines for clinical care that a grantee must follow when meeting this requirement. In addition, the commenter requested that NIDRR revise the priority to include the further development of evidence-based clinical practice guidelines as an area of research funded under this priority.

Discussion: NIDRR does not have a sufficient basis for requiring that its TBIMS Centers adopt specific guidelines.

However, we agree that it is helpful to clarify in the priority that TBIMS centers may adopt practice guidelines as standards. Using standard TBIMS procedures of deliberation and voting, the TBIMS Project Directors could choose to adopt practice guidelines to guide care within the TBIMS Centers. NIDRR expects that the research conducted in the TBIMS Centers will contribute to the development of evidence-based rehabilitation practices through the advancement of knowledge at any stage of research (see NIDRR's proposed Long-Range Plan).

Changes: NIDRR has amended paragraph (a) to clarify that the TBIMS Centers may adopt practice guidelines as standards within the model systems. NIDRR also amended paragraph (c) to clarify that NIDRR expects that research projects will contribute to the development of evidence-based TBI rehabilitation.

Comment: One commenter asked several questions regarding proposed paragraph (g) of the priority, which would require grantees to spend \$5,000 of their total budget towards the costs of a state-of-the-science conference. The commenter asked whether these funds must be used to organize the conference or whether they could be used to support travel to the conference. The commenter also asked for clarification regarding the grant years and budget category

(training vs. research) in which these funds could be budgeted. Finally, the commenter asked about the title and scope of the state-of-the-science conference; specifically, the commenter asked whether the funds would be used to support a "4<sup>th</sup> Interagency Conference on TBI".

Discussion: NIDRR has decided to withdraw the proposed requirement that TBIMS Centers budget to support a state-of-the science conference. Instead, NIDRR is adding language to paragraph (g) of the priority that suggests including a state-of-the-science meeting as one possible means of collaboratively conducting knowledge translation activities that might be used to disseminate research findings from the TBIMS Centers program. TBIMS Centers have the freedom to determine the amount of funds that they might set aside for such activities, including any activities conducted in conjunction with the Model Systems Knowledge Translation Center.

Changes: NIDRR has removed the requirement in proposed paragraph (g) of the priority and redesignated the lettering of the following paragraphs of the final priority accordingly. Language has been added to paragraph (g) of the final priority to provide the option that state-of-the-science meetings could be one means of facilitating dissemination of research findings to stakeholders.

Comment: One commenter asked how NIDRR would assess applicants' capacity to participate in multi-site collaborative research as required in proposed paragraph (e) of the priority.

Discussion: Peer reviewers will use selection criteria under 34 CFR 350.54 to evaluate the quality of applications under this program, including applicants' descriptions of their capacity to engage in collaborative research. Peer review criteria under 34 CFR 350.54(k) are directly applicable to the evaluation of applicants' capacity to engage in multi-site collaborative research.

Changes: None.

Comment: Regarding paragraph (d) of the proposed priority, one commenter requested clarification on the distinction between multi-site research conducted under this priority (the TBIMS Centers Program Priority (CFDA 84.133A-5)) and the research conducted under the separately-funded TBIMS Collaborative Priority (CFDA 84.133A-4, published in the Federal Register on February 1, 2008 (73 FR 6132)). Specifically, the commenter asked whether NIDRR intended to disallow current TBIMS Collaborative grantees from proposing a TBIMS Centers module project under this priority.



Discussion: NIDRR does not intend to prohibit any center funded under the FY 2008-2012 TBIMS Collaborative competition (CFDA 84.133A-4) from applying under the FY 2012 competition using this priority. If a TBIMS Collaborative grantee is also awarded a FY 2012 TBIMS Center grant under this priority, it would be required to participate as a research collaborator in at least one multi-site module project under paragraph (d) of this priority. Its participation in the multi-site module project funded under this priority would need to be distinct from the multi-site research conducted under its TBIMS Collaborative grant.

Changes: NIDRR has revised paragraph (d) of the final priority to clarify that the multi-site module research activities funded under this priority must not be part of a current TBIMS Multi-Site Collaborative Project, which the Department funded under a separate priority.

Comment: One commenter requested clarification regarding proposed paragraph (i) which requires TBIMS Centers to address the needs of individuals with TBI, including individuals from one or more "traditionally underserved populations." Specifically, the commenter asked the Department to clarify what populations would be considered "traditionally underserved" for purposes of this priority.

Discussion: Paragraph (i) of the proposed priority (redesignated as paragraph (h) in the final priority) requires each TBIMS Center to address the needs of individuals with traumatic brain injuries, including individuals from one or more traditionally underserved populations through its project. The Rehabilitation Act authorizes the research activities that are administered by NIDRR, including the research activities under the TBIMS Centers Program. While section 21 of the Rehabilitation Act, titled Traditionally Underserved Populations, does not define the term "traditionally underserved," it does provide an in-depth discussion of populations that experience inequitable treatment and relatively poor outcomes in the vocational rehabilitation process. Section 21 of the Rehabilitation Act specifically mentions groups of racial and ethnic minorities with disabilities, including Latinos, African Americans, Asian Americans, and American Indians with disabilities. There are a wide variety of underserved populations that applicants could focus upon in order to meet this specific requirement. NIDRR does not wish to preclude applicants from proposing specific populations that are relevant in their region, by providing a specific, yet possibly incomplete list of underserved populations. Instead, for purposes of this

priority, we expect applicants to describe how they will fulfill the priority's requirement to address the needs of individuals with TBI from traditionally underserved populations, as that term is described in section 21 of the Rehabilitation Act. The peer review process will evaluate the merits of each application.

Changes: We have amended this paragraph to include a cross-reference to the Rehabilitation Act's discussion of traditionally underserved populations. Also, paragraph (i) of the proposed priority has been redesignated as paragraph (h) in this final priority as part of the redesignation referred to earlier in this notice.

Comment: None.

Discussion: In keeping with prior practice, NIDRR expects the project directors of the TBIMS Centers to participate in two project directors' meetings per year to be held in the greater Washington, DC area. These meetings are critical to the ongoing operations of this network of 16 TBIMS Centers and to the advancement of the collaborative research funded under this priority. Applicants must budget for the costs of having their project directors travel to and participate in these meetings. A TBIMS Center may allow additional center staff to attend with the TBIMS Center's project director, as long as the staff's

attendance is essential for the Center to meet its objectives.

Changes: NIDRR has added paragraph (j) to the final priority. This new paragraph states that the TBIMS Center must ensure that its project director participates in two annual face-to-face TBIMS Center Project Directors' meetings in the greater Washington, DC area.

FINAL PRIORITY:

Priority--Traumatic Brain Injury Model Systems Centers (TBIMS)

The Assistant Secretary for Special Education and Rehabilitative Services announces a priority for the funding of Traumatic Brain Injury Model Systems (TBIMS) Centers under the Disability and Rehabilitation Research Projects (DRRP) program. The TBIMS Centers must provide comprehensive, multidisciplinary services to individuals with traumatic brain injury (TBI) and conduct research that contributes to the development of evidence-based rehabilitation interventions and clinical and practice guidelines.

For purposes of this priority, the term traumatic brain injury or TBI is defined as damage to brain tissue caused by an external mechanical force as evidenced by loss of consciousness or post-traumatic amnesia due to brain

trauma or by objective neurological findings that can be reasonably attributed to TBI on physical examination or mental status examination. Both penetrating and non-penetrating wounds that fit these criteria are included, but, primary anoxic encephalopathy is not.

The TBIMS Centers must generate new knowledge that can be used to improve outcomes of individuals with TBI in one or more domains identified in NIDRR's currently approved Long Range Plan, published in the Federal Register on February 15, 2006 (71 FR 8165): health and function, community living and participation, technology, and employment. Each TBIMS Center must contribute to this outcome by--

(a) Providing a multidisciplinary system of rehabilitation care specifically designed to meet the needs of individuals with TBI. The system must encompass a continuum of care, including emergency medical services, acute care services, acute medical rehabilitation services, and post-acute services. TBIMS Centers may choose to adopt practice guidelines to guide care within the TBIMS Centers, using established TBIMS procedures of deliberation and voting for recommendations that affect all TBIMS Centers;

(b) Continuing the assessment of long-term outcomes of individuals with TBI by enrolling at least 35 subjects

per year into the TBIMS database, following established protocols for the collection of enrollment and follow-up data on subjects (found at [www.tbindsc.org](http://www.tbindsc.org));

Note: TBIMS Centers will be funded at varying amounts up to the maximum award based on the numbers of TBIMS database participants from whom TBIMS Centers must collect follow-up data. TBIMS Centers that have previously been TBIMS grantees with large numbers of database participants will receive more funding within the specified range than TBIMS Centers with fewer participants, as determined by NIDRR after applicants are selected for funding. Applicants must include in their budgets specific estimates of their costs for follow-up data collection. Funding will be determined individually for each successful applicant, up to the maximum allowed, based upon the documented workload associated with the follow-up data collection, other costs of the grant, and the overall budget of the research project.

(c) Proposing and conducting at least one, but no more than two, site-specific research projects to test innovative approaches to treating TBI or to assess outcomes of individuals with TBI. Site-specific research projects must focus on outcomes in one or more domains identified in the Plan: health and function, community living and

participation, technology, and employment, and contribute to the development of evidence-based TBI rehabilitation practices through the advancement of science at any stage of research;

Note: Applicants who propose more than two site-specific research projects will be disqualified.

(d) Participating as a research collaborator in at least one module project. Module projects are research collaborations with one or more TBIMS Centers on topics of mutual interest and expertise. Such module projects must be carried out as part of the TBIMS Centers' activities. The module project research activities funded under this priority must not be part of a current TBIMS Multi-Site Collaborative Project, which the Department funded under a separate priority (see the notice inviting applications, published in the Federal Register on February 1, 2008 (73 FR 6162) and the associated notice of final priority, published in the Federal Register on February 1, 2008 (73 FR 6132));

Note: Applicants should not propose a specific module project in their application. While all TBIMS Centers grantees are required to participate as research collaborators in at least one module project, they are not required to develop any module project on their own.

Immediately following the announcement of awards under this priority, TBIMS Centers that are interested in proposing module projects may identify module topics, identify potential collaborators from among the other TBIMS Centers, and propose research protocols for the potential modules. At the first TBIMS Centers Project Directors' meeting, Project Directors will review, discuss, and decide upon specific module projects to implement. NIDRR staff will facilitate this post-award discussion and negotiation among TBIMS Centers grantees. Once these module projects are agreed upon by the Project Directors, each TBIMS Center must participate in at least one of them.

(e) Demonstrating, in its application, its capacity to successfully engage in multi-site collaborative research on TBI. This capacity includes access to research participants, the ability to maintain data quality, and the ability to adhere to research protocols;

(f) Spending at least 15 percent of its annual budget on participating in a module project, as described in paragraph (d) of this priority;

(g) Coordinating with the NIDRR-funded Model Systems Knowledge Translation Center (MSKTC) (<http://www.msktc.org/>) to provide scientific results and information for dissemination to stakeholders, including



researchers, clinicians, consumers, and policymakers, using a variety of mechanisms that could include state-of-the-science meetings, webinars, Web sites, and other approaches;

(h) Addressing the needs of individuals with TBI, including individuals from one or more traditionally underserved populations, as discussed in section 21 of the Act, 29 U.S.C. 718;

(i) Ensuring that the input of individuals with TBI is used to shape TBIMS research; and

(j) Ensuring that its project director participate in two annual face-to-face TBIMS Center Project Directors' meetings in the greater Washington, DC area.

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the Federal Register. The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an

application by (1) awarding additional points, depending on the extent to which the application meets the priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority, we are particularly interested in applications that meet the priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

This notice does not preclude us from proposing additional priorities, requirements, definitions, or selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use this priority, we invite applications through a notice in the Federal Register.

#### Executive Orders 12866 and 13563

#### Regulatory Impact Analysis

Under Executive Order 12866, the Secretary must determine whether this regulatory action is "significant" and, therefore, subject to the requirements of the Executive order and subject to review by the Office of

Management and Budget (OMB). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action likely to result in a rule that may--

(1) Have an annual effect on the economy of \$100 million or more, or adversely affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or Tribal governments or communities in a material way (also referred to as an "economically significant" rule);

(2) Create serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles stated in the Executive order.

This final regulatory action is not a significant regulatory action subject to review by OMB under section 3(f) of Executive Order 12866.

We have also reviewed this final regulatory action under Executive Order 13563, which supplements and explicitly reaffirms the principles, structures, and

definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, Executive Order 13563 requires that an agency--

(1) Propose or adopt regulations only upon a reasoned determination that their benefits justify their costs (recognizing that some benefits and costs are difficult to quantify);

(2) Tailor its regulations to impose the least burden on society, consistent with obtaining regulatory objectives and taking into account--among other things and to the extent practicable--the costs of cumulative regulations;

(3) In choosing among alternative regulatory approaches, select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity);

(4) To the extent feasible, specify performance objectives, rather than the behavior or manner of compliance a regulated entity must adopt; and

(5) Identify and assess available alternatives to direct regulation, including economic incentives--such as user fees or marketable permits--to encourage the desired behavior, or provide information that enables the public to make choices.

Executive Order 13563 also requires an agency "to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible." The Office of Information and Regulatory Affairs of OMB has emphasized that these techniques may include "identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes."

We are issuing this final priority only on a reasoned determination that its benefits justify its costs. In choosing among alternative regulatory approaches, we selected those approaches that maximize net benefits. Based on the analysis that follows, the Department believes that this regulatory action is consistent with the principles in Executive Order 13563.

We also have determined that this regulatory action does not unduly interfere with State, local, and Tribal governments in the exercise of their governmental functions.

In accordance with both Executive orders, the Department has assessed the potential costs and benefits, both quantitative and qualitative, of this regulatory action. The potential costs are those resulting from statutory requirements and those we have determined as

necessary for administering the Department's programs and activities.

Summary of potential costs and benefits:

The benefits of the Disability and Rehabilitation Research Projects and Centers Programs have been well established over the years in that similar projects have been completed successfully. This final priority will generate new knowledge through research and development.

Another benefit of this final priority is that the establishment of a new DRRP will improve the lives of individuals with disabilities. The new DRRP will provide support and assistance for NIDRR grantees as they generate, disseminate, and promote the use of new information that will improve the options for individuals with disabilities to perform regular activities of their choice in the community.

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Dated: June 6, 2012

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